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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,467	02/24/2004	Denis Alfred Gonzales	CM2599C	8592

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EXAMINER

LEWIS, AMY A

ART UNIT PAPER NUMBER

1614

DATE MAILED: 12/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/785,467

Applicant(s)

GONZALES ET AL.

Examiner

Amy A. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2,4-7,9,10 and 12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2,4-7,9,10 and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of the Case***

The Remarks and Amendments, filed 16 August 2005, have been entered into the application. Accordingly, claims 2, 4-7, 9, and 10 have been amended and claims 1, 3, 8, 11, 13, and 14 have been cancelled.

Claims 2, 4-7, 9, 10, and 12, as filed 16 August 2005, are presented for examination.

### ***Applicant's Remarks will be addressed as follows:***

- Rejection of claim 13 under 35 USC 112 has been rendered moot due to cancellation of the claim.
- Claims 1 and 2 stand rejected under 35 U.S.C. 102(b) as being anticipated by Cherukuri et al. (WO 99/59428). This rejection has been withdrawn in view of amendments to claims, and is moot regarding claim 1 due to its cancellation.
- Claims 1-4 stand rejected under 35 U.S.C. 102(b) as being anticipated by Song et al. (US Pat. 5,128,155). This rejection has been withdrawn in view of amendments to claims, and is moot regarding claims 1 and 3 due to their cancellation.
- Claims 1-4, 7, and 9 stand rejected under 35 U.S.C. 102(b) as being anticipated by Huzinec et al. (US Pat. 5,912,030). This rejection has been withdrawn in view of amendments to claims, and is moot regarding claims 1 and 3 due to their cancellation.
- Claims 1-4, 7, 9, 10, 12, and 13 stand rejected under 35 U.S.C. 102(b) as being anticipated by Van Beem et al. (WO 95/03709). This rejection has been

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withdrawn in view of amendments to claims, and is moot regarding claims 1, 3 and 13 due to their cancellation.

- Claims 5 and 6 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Huzinec et al. (US Pat. 5,912,030). This rejection has been withdrawn in view of amendments to the claims which limit the odor absorbing agent to uncomplexed cyclodextrin.

*The following new grounds of rejection are set forth and necessitated by amendments to the claims:*

***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- 1) Claims 2, 4, 5, 7, 9, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Yajima (US Patent No. 4,267,166).

Yajima teaches “a foul breath preventative agent comprising cyclodextrin as and effective component” (abstract). The reference teaches that the agent can be a chewing gum (see: col. 1, line 50; Example 5 at col. 2, lines 62+; claims 1 and 3). The reference also teaches  $\beta$ -cyclodextrin, as well as mixtures of the  $\alpha$ -,  $\gamma$ -, and  $\beta$ - forms of cyclodextrin (see: col. 1, lines 39-45; Example 7; claims 1, 3, and 9). The reference also teaches a chewing gum comprising a chewing gum base and  $\beta$ -cyclodextrin (see Example 5). The components of the gum of Example 5 also meet the limitations of instant claims 7 and 9

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regarding % by weight and instant claim 5 regarding weight ratios. The preparation of Example 7 as well as the limitation "0.5-50% by weight of cyclodextrin with the balance of said composition being edible carrier" of patented claim 1, meet the weight ratio limitations of instant claims 5, 7, and 9.

Regarding the limitation of having one odor absorbing agent from (a) and (b) of claim 5, the reference teaches uncomplexed  $\beta$ -cyclodextrin as well as  $\beta$ -cyclodextrin in complex with another agent, therefore meeting the limitation of one component from each (a) and (b) of instant claim 5. Further, the reference teaches mixtures containing  $\beta$ -cyclodextrin with a carrier.

Regarding the instant limitation of "uncomplexed cyclodextrin," Yajima does not specify that the cyclodextrin must be complexed with another agent. Further, Yajima states that the agent "comprises cyclodextrin as an active component" and that the agent may consist of cyclodextrin "alone or comprise it and a conventional carrier... such as sugar" (see col. 4, lines 13-17). Thus, the reference teaches the limitation of a cyclodextrin/active inclusion complex of instant claim 10. Therefore absent a showing to the contrary, meets the instant limitation of uncomplexed cyclodextrin as well as an active inclusion complex.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2) Claims 2, 4-7, 9, 10, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yajima (US Patent No. 4,267,166), in view of Ning et al. (US Pub. No. US 2003/0049303 A1), which is available as prior art with a filing date of 15 May 2001.

Yajima is applied as above. Yajima teaches “a foul breath preventative agent comprising cyclodextrin as an effective component” (abstract). The reference teaches that the agent can be a chewing gum (see: col. 1, line 50; Example 5 at col. 2, lines 62+; claims 1 and 3). The reference also teaches  $\beta$ -cyclodextrin, as well as mixtures of the  $\alpha$ -,  $\gamma$ -, and  $\beta$ - forms of cyclodextrin (see: col. 1, lines 39-45; Example 7; claims 1, 3, and 9). The reference also teaches a chewing gum comprising a chewing gum base and  $\beta$ -cyclodextrin (see Example 5). The components of the gum of Example 5 also meet the limitations of instant claims 7 and 9 regarding % by weight and instant claim 5 regarding weight ratios. The preparation of Example 7 as well as the limitation “0.5-50% by weight of cyclodextrin with the balance of said composition being edible carrier” of patented claim 1, meet the weight ratio limitations of instant claims 5, 7, and 9.

Regarding the limitation of having one odor absorbing agent from (a) and (b) of claim 5, the reference teaches uncomplexed  $\beta$ -cyclodextrin as well as  $\beta$ -cyclodextrin in complex with another agent, therefore meeting the limitation of one component from each (a) and (b) of instant claim 5. Further, the reference teaches mixtures containing  $\beta$ -cyclodextrin with a carrier.

Regarding the instant limitation of “uncomplexed cyclodextrin,” Yajima does not specify that the cyclodextrin must be complexed with another agent. Further, Yajima states that the agent “comprises cyclodextrin as an active component” and that the agent may consist of cyclodextrin “alone or comprise it and a conventional carrier...such as sugar” (see col. 4, lines 13-17). Thus, the reference teaches the limitation of a cyclodextrin/active inclusion complex of instant claim 10. Therefore absent a showing to the contrary, meets the instant limitation of uncomplexed cyclodextrin as well as an active inclusion complex.

Yajima does not teach silica.

Ning teaches an oral care confectionery composition, preferably a chewing gum (abstract; paragraph [0064]; claims 1, 8, and 12). The reference also teaches that oral malodour controlling agents include absorbants; absorbants are used to absorb, adsorb, bind, or otherwise complex the volatile oral malodour materials, and examples of such materials include cyclodextrin and silica (paragraph [0056]). The reference also teaches that the composition also contains sweeteners (including bulk sweeteners or high intensity sweeteners) and flavouring agents (paragraphs [0075-0100]). Ning does not specifically teach the cyclodextrin  $\beta$ -cyclodextrin.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include silica in the oral composition of Yajima, having been taught that silica, as well as cyclodextrin, are both known to be used in oral malodor compositions. The skilled artisan would have been motivated to include silica because of its known activity of absorbing and controlling oral malodor.

The skilled artisan would have been further motivated to include silica along with  $\beta$ -cyclodextrin because it is *prima facie* obvious to combine two components known for treating the same condition (i.e. oral malodor) to form a third composition for the same purpose. The following case law is believed to be relevant to the instant claim rejections:

*In re Kerkhoven* (205 USPQ 1069, CCPA 1980) states that "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the same purpose: the idea of combining them flows logically from their having been individually taught in the prior art." Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine silica and  $\beta$ -cyclodextrin, motivated by their having been taught by the prior art to be useful in treating oral malodor, consonant with the reasoning of the cited case law.

Therefore, the invention as a whole would have been *prima facie* obvious.

***Pertinent Art:***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.



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- Dodd et al. (US Patent No. 6,656,456 B2), which teaches zeolites, silica gel, silica molecular sieves, and cyclodextrins (including  $\beta$ -cyclodextrin and uncomplexed cyclodextrins) as odor controlling agents. See: col. 3 line 35-col 5, line 51). This reference is considered an equivalent teaching to the Ning reference as to the odor controlling properties of silica and cyclodextrins.

### *Conclusion*

This action is non-final. Claims 2, 4-7, 9, 10, and 12 are rejected. No claims are allowed.

### Contact Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy A. Lewis whose telephone number is (571) 272-2765. The examiner can normally be reached on Monday-Friday, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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